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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,745	04/09/2004	Michael Snyder	1030.004	1863

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,745	SNYDER ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 21-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 08/20/2009.

Claims 11 and 21-24 previously presented. Claims 25-34 are currently added.

Claims 11, 21-34 are pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11, 21, 24-26, 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smedley et al. (US 7,163,543, currently listed on PTO 892) combined with Peyman (US 7,354,574, previously presented).

Applicant Claims

Present claim 11 is directed an implantable device, comprising:

a) an implantable elongated hollow glaucoma drainage tube including a solid walled plastic lumen having a lumen section shaped as a circle and including a flow passage so that when the tube is implanted within an eye the tube has a first end located in a first portion of an eye and a second end located in a second portion of the eye and the flow passage spans between the first end and the second end; and

b) a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen that is filled with the sustained release medium to define a head

space passage that increases its degree of opening over time as matter is passed through the lumen; wherein the lumen has a circular cross section fixed inner and outer dimension, defining a lumen diameter, the tube includes a plurality of openings of a fixed size and shape, through which the sustained release medium escapes, and the sustained release medium comprises a solid material.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Smedley teaches glaucoma treatment by permitting aqueous to flow out of the anterior chamber of the eye through a stent to Schlem's canal with one end of the stent positioned in the anterior chamber and a second end positioned in the Schlem's canal (abstract; col.3, lines 36-47). The stent contains pharmaceuticals that reduce, inhibit or slow the effects of glaucoma and heals any injury of the eye (col.3, lines 17-31). The stent is made of biocompatible material that can be metal, i.e. solid, and is coated by therapeutic agent (col.7, lines 55-63). The stent has lumen that can be circular, and has plurality of side openings (col.8, lines 1-3, 12-20; figure 3). Smedley teaches that the device can be coated or loaded within interior location, such as pores, with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device (col.10, lines 31-38, 60-65). The coating is expected to cover the openings as required by claims 24, 32-34. The teaching of the reference that "the therapeutic agent can be loaded in interior location of the stent", would have suggested inner surface of the lumen of the stent or within the wall.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Smedley teaches loading of the device with slow release therapeutic agent and teaches interior loading, however, the reference does not explicitly teach sustained release caprolactone polymer as a release medium as instantly claimed by claim 11.

Peyman teaches implantable composition for treating ocular diseases (abstract). The composition comprises antimicrobial agent in polymer matrix of polycaprolactone contained in a diffusible walled reservoir providing sustained release composition formulated to release non-toxic therapeutic amount of the antimicrobial agent over the time (col.2, lines 9-15; col.3, lines 18-25, 42-48, 56-65).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen with one end positioned in the anterior chamber and a second end positioned in the Schlem's canal that can be loaded in the interior with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device as taught by Smedley, and provide the therapeutic agent in a polymer matrix of polycaprolactone as taught by Peyman. One would have been motivated to do so because Peyman teaches

that polycaprolactone matrix provides sustained release of the contained therapeutic agent in non-toxic therapeutic amount over the time. One would reasonably expect formulating glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent in order to slowly release non-toxic doses of the therapeutic agent to the surrounding and injured tissues.

Regarding the limitation of increase of the degree of opening of the head space passage as claimed by claim 11, 24, 32-31, the combined teaching of Smedley and Peyman provides glaucoma drainage tube having in the interior a polymer composition comprising caprolactone, and it is expected that caprolactone will be eroded slowly to release the therapeutic agent, therefore forming the head space passage as the polymer degrades, and it is expected that by time and with erosion of the caprolactone matrix, more space is created in the stent lumen.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

5. Claims 22, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Smedley and Peyman and further in view of Bardenstein (US 4,743,255 previously recited).

The combined teaching of Smedley and Peyman are previously discussed as set forth in this office action.

However, the references do not teach radiologically detectable marker material as claimed by claims 22, 27 and 28.

Bardenstein teaches intraocular implantable material that can be incorporated with radio-opaque marker material for follow up using simple radiological technique without resorting to complex imaging techniques (col.1, line 64-col.2, line 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent as taught by the combined teachings Smedley and Peyman, and further add radio-opaque material that can be detected by radiology to the stent as taught by Bardenstein. One would have been motivated to do so because Bardenstein teaches that radio-opaque marker material helps follow up using simple radiological technique without resorting to complex imaging techniques. One would reasonably expect formulating glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent and radio-opaque marker material that helps follow up by simple radiology technique.

6. Claims 23, 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Smedley and Peyman and further in view of Wong et al. (US 6,692,759 previously recited).

The combined teaching of Smedley and Peyman are previously discussed as set forth in this office action.

However, the references do not teach layered sustained release material as claimed by claims 23, 29-31.

Wong teaches ocular implantable devices for sustained release of active substances including therapeutic agents to tissues adjacent to the area of implantation (abstract; col.3, lines 32-38; col.5, lines 17-20; col.8, lines 45-64). The implant is multi-layered to deliver two or more active agents to reach different surrounding regions and particularly useful for delivering two or more active substances (col.6, lines 58-63; col.9, lines 26-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent as taught by the combined teachings Smedley and Peyman, and further formulate the matrix as a multilayered matrix as taught by Wong. One would have been motivated to do so because Wong teaches that multi-layered implantable delivery device is particularly useful for delivering one or more active substances to the surrounding regions. One would reasonably expect formulating glaucoma treatment stent having in the interior multilayered polycaprolactone matrix containing more than one therapeutic agent to provide more than one beneficial effect to the surrounding regions to patient in need.

Response to Arguments

7. Applicant's arguments with respect to claim11, 21-34 have been considered but are moot in view of the new ground(s) of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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